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PTO/SB/05 (2/98)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	
First Inventor or Application Identifier	Carl W. Hastings
Title	Performance-Enhancing Dietary Supplement
Express Mail Label No.	TB828221163 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231

1. [X] * Fee Transmittal Form (e.g., PTO/SB/17) (Submit an original and a duplicate for fee processing)
2. [X] Specification [Total Pages 15]
   (preferred arrangement set forth below)
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings (if filed)
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [X] Drawing(s) (35 U.S.C. 113) [Total Sheets 0]
4. Oath or Declaration [Total Pages 17]
   a. [ ] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d)) (for continuation/divisional with Box 17 completed) [Note Box 5 below]
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).
5. [ ] Incorporation By Reference (useable if Box 4b is checked) The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered to be part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. [ ] Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
   a. [ ] Computer Readable Copy
   b. [ ] Paper Copy (identical to computer copy)
   c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. [ ] Assignment Papers (cover sheet & document(s))
9. [ ] 37 C.F.R.§3.73(b) Statement (when there is an assignee) [ ] Power of Attorney
10. [ ] English Translation Document (if applicable)
11. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
12. [ ] Preliminary Amendment
13. [X] Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
14. [X] * Small Entity Statement(s) (PTO/SB/09-12) [ ] Statement filed in prior application, Status still proper and desired
15. [ ] Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. [X] Other: General Authorization Under 37 CFR 1.136(a)(3)

* NOTE FOR ITEMS 1 & 14: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

17. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:
    [ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: _____/_____
    Prior application information: Examiner _____ Group / Art Unit: _____

18. CORRESPONDENCE ADDRESS

[ ] Customer Number or Bar Code Label (Insert Customer No. or Attach bar code label here) or [ ] Correspondence address below

Name	John B. Lungmus				
	Tilton, Fallon, Lungmus & Chestnut				
Address	100 South Wacker Drive				
	Suite 960				
City	Chicago	State	Illinois	Zip Code	60606
Country	USA	Telephone	312/456-8000	Fax	312/456-7776

Name (Print/Type)	John B. Lungmus	Registration No. (Attorney/Agent)	18,566
Signature	John B. Lungmus	Date	10/20/98

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FEE TRANSMITTAL

Patent fees are subject to annual revision on October 1.
These are the fees effective October 1, 1997.
Small Entity payments must be supported by a small entity statement, otherwise large entity fees must be paid. See Forms PTO/SB/09-12.
See 37 C.F.R. §§ 1.27 and 1.28.

TOTAL AMOUNT OF PAYMENT ($) 1060.00

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Carl W. Hastings
Examiner Name	
Group / Art Unit	
Attorney Docket No.	

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 20-1111
Deposit Account Name:

[X] Charge Any Additional Fee Required Under 37 C.F.R. §§ 1.16 and 1.17 [ ] Charge the Issue Fee Set in 37 C.F.R. § 1.18 at the Mailing of the Notice of Allowance

2. [X] Payment Enclosed: [X] Check [ ] Money Order [ ] Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	790	201	395	Utility filing fee	790.00
106	330	206	165	Design filing fee	
107	540	207	270	Plant filing fee	
108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) 790.00

2. EXTRA CLAIM FEES

	Extra Claims		Fee from below	Fee Paid
Total Claims 14	-20** = 0	X	22	= 0
Independent Claims 2	- 3** = 0	X	82	= 0
Multiple Dependent			270	= 270

**or number previously paid, if greater; For Reissues, see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	22	203	11	Claims in excess of 20
102	82	202	41	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim, if not paid
109	82	209	41	** Reissue independent claims over original patent
110	22	210	11	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 1060.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet.	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	950	217	475	Extension for reply within third month	
118	1,510	218	755	Extension for reply within fourth month	
128	2,060	228	1,030	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,320	241	660	Petition to revive - unintentional	
142	1,320	242	660	Utility issue fee (or reissue)	
143	450	243	225	Design issue fee	
144	670	244	335	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	790	246	395	Filing a submission after final rejection (37 CFR 1.129(a))	
149	790	249	395	For each additional invention to be examined (37 CFR 1.129(b))	

Other fee (specify) _____
Other fee (specify) _____

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 530.00

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	John B. Lungmus			Reg. Number	18,566
Signature		Date	10/20/98	Deposit Account User ID	20-1111

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Applicant or Patentee: Carl W. Hastings et al
Serial or Patent No.: _____
Filed or Issued: _____
For: Performance-Enhancing Dietary Supplement

Attorney's Docket No.: _____

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) AND 1.27 (d)) - SMALL BUSINESS CONCERN

I hereby declare that I am

[ ] the owner of the small business concern identified below:
[X] an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN Reliv' International, Inc.

ADDRESS OF CONCERN 136 Chesterfield Industrial Blvd.
Chesterfield, Missouri 63006

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or as the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled Performance-Enhancing Dietary Supplement
by inventor(s) _____ described in

[ ] the specification filed herewith
[ ] application serial no. _____, filed _____
[ ] patent no. _____, issued _____

If the rights held by the above identified small business are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27)

FULL NAME _____
ADDRESS _____
[ ]INDIVIDUAL [ ]SMALL BUSINESS CONCERN [ ]NONPROFIT ORGANIZATION

FULL NAME _____
ADDRESS _____
[ ]INDIVIDUAL [ ]SMALL BUSINESS CONCERN [ ]NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like to made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code,and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Carl W. Hastings
TITLE IN ORGANIZATION Ex. V.P.
ADDRESS OF PERSON SIGNING 18180 Bent Ridge Drive
Glencoe, Missouri 63098

SIGNATURE Carl W. Hastings, Ex. V.P. DATE 10/19/98

Application

For

United States Letters Patent

PERFORMANCE-ENHANCING DIETARY SUPPLEMENT

Carl W. Hastings
David J. Barnes
Christine A. Daley

PERFORMANCE-ENHANCING DIETARY SUPPLEMENT

Abstract of the Disclosure

A dietary supplement for enhancing physical performance of human subjects is disclosed. The supplement in dry, finely-divided form includes as a major ingredient a soy protein isolate containing at least 80% protein on a moisture-free basis with lesser amounts of carbohydrate, free form amino acids, medium chain triglycerides, creatine monohydrate, l-carnitine, grape seed extract, coenzyme Q10, piper nigrum extract, and alpha lipoic acid. In a preferred embodiment, the supplement also includes minor amounts of conjugated linoleic acid and phosphatidylserine/phosphatidylcholine complex.

Background and Summary of the Invention

Soy protein is known to be the only plant protein equal in quality to protein derived from milk, meat or eggs. The most concentrated source of soy protein is soy protein isolate which, preferably, is manufactured by water extraction (rather than alcohol extraction) of defatted and dehulled soybeans and therefore retains its natural isoflavones. On a Protein Digestability Corrected Amino Acid Score (PDCAAS) of 1.0, soy protein isolate is highly digestible and meets or exceeds the essential amino acid requirements for children and adults. Such an isolate contains naturally high levels of branched chain amino acids to provide an energy source during physical activity, it having been reported that during the first 20 minutes of strenuous sports activity muscle glycogen serves as the primary energy source but that after 20 minutes bioavailable fatty acids and branched chain amino acids become the primary energy sources. Isolated soy protein is therefore known to be a highly desirable energy source for athletes that also helps to reduce muscle fatigue and enhance muscle recovery.

In addition, isolated soy protein is known to contain naturally high levels of arginine which stimulates the release of anabolic hormones to promote muscle formation, enhances wound healing, helps to maintain a strong and healthy immune system, and is believed to be beneficial in reducing stress. Such isolated soy protein is also a good source of naturally occurring iron, a fact of considerable importance for athletes who are highly susceptible to "sports anemia" resulting from loss of iron occurring in sweat and urine.

There is compelling evidence from both animal and human studies that, compared to animal protein, soy protein also

reduces elevated levels of LDL-cholestrol. A meta-analysis of 38 clinical studies reported in 29 scientific articles has provided quantitative data showing that consumption of soy protein rather than animal protein significantly decreases blood concentrations of total cholestrol, LDL-cholestrol, and triglycerides in humans. Anderson J.W., Johnstone B.M. and Cook-Newell M.E., NEJM 1995; 333:276-282. Such studies provide motivation for recommending the increased consumption of soy protein, particularly isolated soy protein, as part of an integrated dietary approach to the control of hypercholesterolemia. It is therefore believed that the intake of protein isolates may be advantageous to athletes and others concerned about the risk of developing coronary heart disease.

The composition of this invention is a performance-enhancing dietary supplement that contains soy protein isolate in combination with free form amino acids and also other specified components, particularly medium chain triglycerides, with the latter coacting to improve the absorption by the body of the amino acids and calcium present in the soy protein isolate and the additional amino acids included in free form in the supplement. In addition, the medium chain triglycerides produce ketone bodies that burn preferentially to muscle tissue for energy, thereby reducing muscle loss. Such medium chain triglycerides provide over twice the energy of carbohydrates (they produce 8.3 calories per gram compared to 4 calories per gram for carbohydrates) and are absorbed as quickly as glucose without significant effect on insulin production.

Other constituents of the dietary supplement include creatine monohydrate which helps reduce muscle fatigue and

rebuild lean muscle mass, l-carnitine which is a non-protein amino acid that acts as a biocatalyst to increase the use of fat for energy during exercise, coenzyme Q10 that, like l-carnitine, is important for its role in burning energy inside muscle cells at the mitochondria, grape seed extract and alpha lipoic acid, both of which are potent free radical scanvengers and chelators of toxic metals, and piper nigrum extract which increases the uptake of nutrients and their metabolic utilization. The supplement also preferably includes conjugated linoleic acid (CLA), a natural fatty acid that reduces body fat and increases muscle tone by helping the body extract more energy from less food, and a phosphtidylserine/ phosphtidylcholine complex which functions as a cell membrane nutrient and a building block for the major membrane systems crucial to the survival and functioning of all cells. The supplement may also include one or more flavoring agents, such as vanilla extract, and processing agents such as lecithin which also lend solubility to the product.

The dietary supplement is provided as an essentially dry mixture in finely-divided (powdered) form with the recommended daily serving being about 26g to about 78g, depending on the level and intensity of physical activity involved. Individuals on an intense physical training regiment will gain optimal results at the higher levels of consumption whereas those on moderate or casual workout regimens will require less. A serving of at least 26g per day is believed necessary to maintain optimal benefits. The powder is soluble in water and it is recommended that each daily serving be mixed with juice, water, milk, or any other drinkable non-alcoholic beverage.

Detailed Description of Preferred Embodiment

A major ingredient of the dietary supplement of this invention is soy protein isolate containing at least 80% protein, preferably at least 90% protein, on a moisture-free basis. While alcohol extracted protein isolate may be used, it is preferred that the isolate be water extracted so that it retains its natural isoflavones. Isoflavones found naturally in soy are believed to inhibit the resorption of bone, it being noted that a synthetic isoflavone found effective in decreasing bone loss is similar in structure to soy bean isoflavones. Isolated soy protein suitable for use in the dietary supplement of this invention is commercially manufactured by water extraction of protein from defatted and dehulled soy beans and is heat treated during processing to insure inactivation of trypsin inhibitors. While isolated soy protein is commercially available from a number of sources, it is believed that a particularly effective soy protein isolate is marketed under the designation "Supro XT 12" by Protein Technologies International, St. Louis, Missouri. Such isolate contains naturally high levels of branched chain amino acids as well as high levels of arginine, iron, and calcium. The essentially dry blend that constitutes the dietary supplement should contain about 55% to 70% by weight of such soy protein isolate.

Also included in the supplement is about 1% to 3% by weight of an amino acid premix composed of two or more free form amino acids selected from the group consisting of l-leucine, l-glutamine, l-alanine, glycine, l-arginine, l-lysine and ornithine alpha-ketogluterate. It is preferred that at least four of the free form amino acids be present in the supplement, namely, l-leucine, l-glutamine, l-alanine and glycine, and ideally all seven

should be included. L-leucine is known to make up about one third of muscle protein and provides the ingredients for the manufacture of alanine and other essential biochemical components in the body, some of which are utilized for the production of energy. L-glutamine is known to promote anabolic conditions in muscle cells and increase the rate of protein synthesis. Glutamine indirectly promotes growth by increasing the hydration state of muscle cells. When cells are swollen with water, this inhibits the breakdown of protein, glycogen and glucose. Glutamine stimulates protein and glycogen synthesis. Conversely, if a cell becomes dehydrated, it shrinks and immediately goes into a catabolic state that breaks down the muscle's vital proteins.

L-alanine is an important source of energy for muscle tissue as well as for the brain and central nervous system. Additionally, it strengthens the immune system by producing antibodies and helps in the metabolism of sugars and organic acids. Glycine helps to trigger the release of oxygen to the energy-requiring cell-making process and is also known to be important in the manufacture of hormones responsible for a strong immune system.

It is known that l-arginine causes the release of growth hormones and is considered crucial for optimal muscle growth and tissue repair. It also promotes wound healing and regeneration of the liver, and studies have shown that it has improved immune responses to bacteria, viruses and tumor cells.

L-lysine is known to be important in insuring the adequate absorption of calcium. It also helps to form collagen and aids in the production of antibodies, hormones and enzymes. Ornithine alpha-ketoglutarate is an amino

acid that improves performance in hypercatabolic states associated with such activities as vigorous sports and weightlifting. It has been noted that l-ornithine and alpha-ketoglutarate work synergistically in hypercatabolic states to achieve several favorable intermediate outcomes. Ornithine alpha-ketoglutarate reduces the rate at which ammonia accumulates. The nitrogen-sparing quality of ornithine alpha-ketoglutarate may be related to its ability to reduce the rate of glutamine loss, it being known that glutamine plays an important role in protein turnover during the catabolic states. As a result of these intermediate outcomes, ornithine alpha-ketoglutarate increases endurance, reduces muscle fatigue and shortens recovery time. In addition, it increases production of human growth hormone which in turn increases muscle mass.

Absorption by the body of the amino acids provided by this supplement both in free form and as branched chain amino acids in the soy protein isolate is enhanced by the inclusion of medium chain triglycerides which should be present in the amount of about 1.5% to about 2.5% by weight. Medium chain triglycerides (MCTs) are unique fatty acids that behave differently from all other fats and provide energy more like carbohydrates. They are also known as capric and caprylic fatty acids, and research studies published in medical and academic journals describe numerous benefits from the ingestion of MCTs. Of particular importance in the dietary supplement of this invention, MCTs improve the absorption of the amino acids that are critical for muscle tissue repair. They also improve the absorption of calcium, magnesium and other minerals needed for the metabolism of carbohydrates and amino acids and for improving muscle contraction response time. The MCTs therefore coact with the soy protein

isolate and the free form amino acids, and with other ingredients of the supplement to improve the absorption of the amino acids. They also have a cholesterol lowering effect and are known to decrease the absorportion of cholesterol in the intestine.

Further, MCTs decrease the absorption of oils, fats and cholesterol while reducing muscle tissue breakdown during dieting. It has been noted that MCTs provide about twice the energy of carbohydrates and avoid the false fatigue created by eating simple sugars because, while MCTs are absorbed as quickly as glucose, they have no significant effect on insulin production.

The dietary supplement should include about 20% to 30% by weight of a carbohydrate, particularly fructose. The fructose not only supplies an important energy source but also renders the supplement more palatable, masking other ingredients that despite their functional importance might otherwise produce a somewhat unfavorable taste sensation for some users. If desired, the supplement may also include suitable artificial and natural flavoring agents, such as a vanilla flavoring agent, but it is to be understood that the inclusion of such agents is optional and non-critical.

It is known that energy consumed by muscles is largely in the form of adenosine triphosphate (ATP) and that during short-term, high intensity exercise the demand by working muscles for ATP increases to several hundred times the requirement of muscles at rest. Since ATP can be stored only to a limited extent in muscle cells, maintaining peak performance requires constant replenishment of ATP levels.

The primary resupplier of ATP levels for short-duration, high intensity exercise is the amino acid creatine, about 60% of which is stored in skeletal muscle tissue in the form of creatine phosphate. During muscle contraction, creatine phosphate converts adenosine diphosphate (ADP) to ATP, thereby replacing the ATP consumed during exericse. Muscle fatigue occurs when the supply of creatine phosphate is exhausted and ADP can no longer be converted to the necessary ATP.

Neither creatine phosphate nor ATP can be directly supplemented in the diet; however, higher levels of creatine may be derived from creatine monohydrate, a form of creatine which has been shown to raise total plasma levels of creatine. Creatine monohydrate is therefore included in the dietary supplement of this invention to shorten the time necessary for the body to generate replacement creatine phosphate and thus significantly reduce muscle recovery time between short duration, high intensity activities. The weight percent of such creatine monohydrate in the dietary supplement should fall within the range of about 1.5% to 2.5%.

Recent studies have shown that athletes who supplement their diet with l-carnitine convert fat to energy more efficiently. L-carnitine is a non-protein amino acid that functions primarily in the body as a biocatalyst. Fats are burned for energy inside muscle cells at the mitochondria, but such fats are stored in adipose cells and cannot pass through the mitochondria unless they are transported by l-carnitine. Thus, the amount of fat burned depends on the level of l-carnitine in the muscle, and recent studies have indicated that athletes supplementing their diet with l-carnitine significantly increase the use of fat for

energy during exercise. This dietary supplement includes l-carnitine to the extent of about 0.18% to 0.28% by weight to increase the burning of fat for energy during exercise as well as to inhibit the buildup of lactic acid in muscle, reduce muscle fatigue, decrease ketone levels in blood, and help to increase high density lipoproteins (HDL) while lowering low density lipoproteins (LDL) in the blood.

The dietary supplement disclosed herein also includes about 0.025% to 0.035% by weight coenzyme Q10 and about 0.01% to 0.02% by weight piper nigrum extract, the latter being commericially available under the designation "Bioperine" from Sabinsa Corporation, Piscathaway, New Jersey. Coenzyme Q10, first isolated from the heart muscle of cattle approximately 40 years ago, has been found to be an important component in the energy production process in cell mitochondria and more recently has been used clinically to improve the condition of patients with congestive heart failure. Through double blind studies, it has been demonstrated that the bioavailability of coenzyme Q10 is significantly increased by the co-administration of piper nigrum extract. As noted in Majeed et al patent 5,536,506, the disclosure of which is incorporated herein by reference, the metabolic pathways for a nutrient and a drug are different in that a nutrient sustains basic metabolism and physiological functions of an organism while a drug is utilized as an adjunct to basic metabolism to restore homeostasis to the physiological functions. In the context of this invention, piper nigrum extract is considered to increase the absorption of nutrients and to increase their metabolic utilization. Its inclusion in this nutritional supplement is intended to enhance the crossing-over of nutrients and botanical compounds through

biological barriers such as, but not limited to, the gastrointestinal epithelium.

The dietary supplement also includes metabolic antioxidants in the form of grape seed extract (0.15% to 0.25% by weight) and alpha lipoic acid (0.0001% to 0.0003% by weight). Studies have shown that the biologically active flavonoids that are concentrated inside red grape seeds contain some of the most powerful antioxidants yet discovered. A particularly effective grape seed extract is commercially available under the designation "ActiVin" from Interhealth Nutritionals Inc., Concord, California; the antioxidant activity of that extract has been shown to be significantly greater than that of vitamins E, C, and beta-carotene, all of which are known to be powerful antioxidants that help the body fight free radicals that have been implicated in a multitude of serious health conditions. In addition, the biologically active flavonoids of the grape seed extract appear useful in helping to maintain normal blood platelet function and reduce blood platelet stickiness, thereby helping to maintain proper cardiovascular health.

Alpha lipoic acid is a coenzyme that participates in converting blood sugar (glucose) into energy and, in addition, is an antioxidant nutrient that networks with other antioxidants, including grape seed extract and vitamins C, E, and A, in quenching free radicals. It is understood that the other antioxidant nutrients function more effectively when there is more lipoic acid available than what is tied up in use by the body as a coenzyme. Lipoic acid is easily absorbed and is readily bioavailable.

In a preferred embodiment of the invention, the dietary supplement also includes conjugated linoleic acid (about

00.5% to 1.5% by weight) and a phosphatidylserine/ phosphatidylcholine complex (about 0.25% to 0.35% by weight). Conjugated linoleic acid (CLA) is an essential fatty acid that reduces body fat and increases muscle tone by helping the body extract more energy from less food. While CLA is believed to be commercially available from a number of sources, one commercial product is marketed under the designation "Tonalin" by PharmaNutrients, Inc., Norway. Studies with CLA have revealed as much as a 20% reduction in body fat resulting from the ingestion of CLA, and other studies have shown that it acts as an active anti-carcinogen.

Phosphatidylserine/phosphatidylcholine has been referred to as a "complex" but that term is used broadly in this context to include mixtures as well as interrelated chemical structures. Phosphatidylserine is a natural soy-derived phospholipid that is known to be effective in suppressing cortisol levels. Cortisol, at the cellular level, plays an important regulatory function in the metabolism of protein, fat, carbohydrate, sodium and potassium. However, cortisol is also a catabolic stress hormone that rises in response to exercise and may interfere with training and atheletic performance by causing breakdown of muscle tissue. Therefore, phosphatidylserine may be useful to bodybuilders, powerlifters, runners, cyclists, rollers, swimmers and other high performance athletes to increase the rate of protein (muscle) synthesis during periods normally marked by muscle breakdown and to protect against the loss of amino acids, glucose, potassium and, potentially, creatine from muscle cells. It is believed to enhance the uptake of vital nutrients into muscle tissue during and after

training and to accelerate muscle recovery following training.

Phosphatidylcholine is a cell membrane nutrient and a building block for the major membrane systems crucial to the survival and functioning of all cells. It has long been known as a nutritional supplement, but it has now been recognized for its effective benefits for liver function. In addition, when used in a nutritional supplement, it helps to replenish blood choline levels.

The dietary supplement optionally includes flavoring agents (0% to 3%) and a processing agent such as lecithin (0% to 3%). In the context of this invention, lecithin is considered useful primarily as a blending agent that also improves the solubility of the dietary supplement as a whole. It is commonly used in foods as an emulsifier, release agent, and instantizing agent. However, to the extent that lecithin is a complex mixture of phospholipids such as phosphatidylcholine and other substances, it is also believed to be a nutritional supplement.

The following examples are not intended to be limiting in any way, but demonstrate some of the preferred embodiments of the present invention.

Example 1

A soy-based performance-enhancing dietary supplement of this invention contains the following ingredients in the percentages indicated: soy protein isolate (Supro XT12) about 61.9%, fructose 27.7%, amino acid premix (consisting of l-leucine l-glutamine, l-alanine, glycine, l-arginine, l-lysine and orinthine alpha-ketoglutarate) 2.7%, CLA (Tonalin) 0.1%, phosphatatidylserine/phosphatidylcholine complex (Corti PS 20) 0.3%, medium chain triglyceride (MCT) powder 1.9%, creatine monohydrate 1.9%, l-carnitine 0.2%,

grape seed extract (ActiVin) 0.2%, coenzyme Q10 0.03%, piper nigrum extract (Bioperine) 0.01%, alpha lipoic acid 0.0002%. The supplement also includes lecithin, primarily as a blending agent, 1.3%, and flavoring agents (BBA Vanilla 14199) 1.7%.

Using a conventional plow blender set for continuous mixing, the fructose is first introduced into the mixing chamber with the blender in operation, and the lecithin and CLA (Tonalin) are added gradually. The choppers are then turned on for approximately 2 minutes, followed by the addition of other dry ingredients in the following sequence: Supro XT 12, amino acid premix, Corti PS 20, creatine monohydrate, MCT powder, Bioperine, ActiVin, alpha lipoic acid, coenzye Q10, l-carnitine, and flavoring agents. The choppers are again turned on for a period of an additional 2 minutes to produce a uniformly-mixed dietary supplement embodying the invention.

The dietary supplement prepared in accordance with this example takes the form of a fine powder to be consumed enterally as a beverage. One to three scopes (26g to 78g) of the powder are mixed with water, juice, milk or any other suitable beverage, and the recommend serving is then consumed once each day.

Example 2

A dietary supplement may be prepared in accordance with Example 1 in which the amino acid premix is composed of the following ingredients and percentages (per total premix): l-glutamine 22.2%, l-arginine 22.2%, l-leucine 27.8%, l-lysine 11.1%, l-alanine 5.6%, glycine 5.6%, l-ornithine alpha-ketoglutarate 5.5%

Example 3

A dietary supplement may be prepared in accordance with Example 1 in which amino acid premix is 1.63% by weight and

consists of four amino acids in the following percentages (per total premix): l-leucine 45.4%, l-glutamine 36.4%, l-alamine 9.1%, glycine 9.1%.

While in the foregoing we have disclosed embodiments of the invention in considerable detail for purposes of illustration, it will be understood by those skilled in the art that many of these details may be varied without departing from the spirit and scope of the invention.

The Claims

1. A soy-based performance-enhancing dietary supplement comprising an essentially dry mixture of the following ingredients in a daily serving of about 26g to 78g: 55% to 70% soy protein isolate containing at least 80% protein on a moisture-free basis; 20% to 30% carbohydrate consisting essentially of fructose; 1% to 3% of an amino acid premix comprising two or more free form amino acids selected from the group consisting of l-leucine, l-glutamine, l-alanine, glycine, l-arginine, l-lysine and ornithine alpha-ketoglutarate; 1.5% to 2.5% medium chain triglycerides; 1.5% to 2.5% creatine monohydrate; 0.18% to 0.28% l-carnitine; 0.15% to 0.25% grape seed extract; 0.025% to 0.035% coenzyme Q10; 0.01% to 0.02% piper nigrum extract; and 0.0001% to 0.0003% alpha lipoic acid.

2. The dietary supplement of Claim 1 in which said amino acid premix includes the following amino acids: l-leucine, l-glutamine, l-alanine and glycine.

3. The dietary supplement of Claim 2 in which said amino acids are present in the following percentages per total weight of premix: l-leucine 35% to 45%, l-glutamine 30% to 40%, l-alanine 5% to 15%, glycine 5% to 15%.

4. The dietary supplement of Claim 1 in which said mixture also includes 0.05% to 0.15% conjugated linoleic acid.

5. The dietary supplement of Claims 1, 2 or 4 in which said mixture also includes 0.25% to 0.35% phosphatidylserine/ phosphatidylcholine complex.

6. The dietary supplement of Claims 1, 2 or 4 in which said soy protein isolate is water extracted and includes retained isoflavones.

7. The dietary supplement of Claim 1 in which said amino acid premix includes all seven of said amino acids of said group.

8. The dietary supplement of Claim 7 in which said amino acids are present in the following percentages per total weight of premix: l-leucine 25% to 30%, l-glutamine 20% to 25%, l-alanine 4% to 7%, glycine 4% to 7%, l-arginine 20% to 25%, l-lysine 8% to 15%, ornithine alpha-ketoglutarate 4% to 7%.

9. The dietary supplement of Claim 1 in which said mixture also includes 0% to 3% lecithin and 0% to 3% one or more flavoring agents.

10. A soy-based performance-enhancing dietary supplement comprising an essentially dry mixture of the following ingredients in a daily serving of about 26g to 78g: about 61.9% soy protein isolate containing at least 80% protein on a moisture-free basis, about 27.7% carbohydrate consisting essentially of fructose, about 2.7% of an amino acid premix comprising two or more free form amino acids selected from the group consisting of l-leucine, l-glutamine, l-alanine, glycine, l-arginine, l-lysine and ornithine alpha-ketoglutarate, about 1.9% medium chain triglycerides, about 1.9% creatine monohydrate; about 0.2% l-carnitine; about 0.2% grape seed extract, about 0.1% conjugated linoleic acid, about 0.3% phosphatidylserine/phosphatidylcholine complex, about 0.03% coenzyme Q10, about 0.01% piper nigrum extract, about 0.0002% alpha lipoic acid, about 1.3% lecithin, and about 1.7% flavoring agents.

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Performance-Enhancing Dietary Supplement

the specification of which:

___X___ is attached hereto

_____ was filed on _____
Application Serial No._____
and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a) (a copy of which is attached).

I hereby claim foreign priority benefits under Title 35, United States code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

			PRIORITY	CLAIMED
_____	_____	_____	_____YES	_____NO
(Number)	(Country)	(Day/Month/Year Filed)		
			PRIORITY	CLAIMED
_____	_____	_____	_____YES	_____NO
(Number)	(Country)	(Day/Month/Year Filed		

POWER OF ATTORNEY: As named inventor, I hereby appoint the following attorney(s) and/or agent(s) with full powers of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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§1.56 Duty to Disclose Information Material to Patentability

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosectuion of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. there is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this specification are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

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